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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,866	03/24/2005	Amir Loshakove	088/04468	6201

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EXAMINER	
BACHMAN, LINDSEY MICHELE	

ART UNIT	PAPER NUMBER
3734	

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/528,866	LOSHAKOVE ET AL.	
	Examiner	Art Unit	
	Lindsey Bachman	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the evaluator containing a flat, elongate element, two slots of different opening sizes, and a first edge gauge (Claims 33-37) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1-7, 12, 20-23, 25-32, 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor, et al. (US Patent 6,387,108).

5. Claim 1 and 7: Taylor'108 discloses an instrument for making an incision in a cardiac vessel containing a sterile penetration tip (2) to pierce the wall of a vessel (column 3, lines 46-49); an arcuate section (4) having a cutting edge (5) defined on an inner portion thereof, extending from the penetration tip; the arcuate section contains at least one incision length marking thereon. This could be any marking on the blade such as the point at which the cutting edge (5) ends.

6. Claim 2: The tip taught by Taylor'108 is adapted to prevent tearing (column 2, lines 53-55).

7. Claim 3: Taylor'108 discloses a handle (8).

8. Claim 4 and 5: Taylor'108 discloses two incision length markings (end of cutting edge 5 at the distal end, end of cutting edge 5 at proximal end).

9. Claim 6: The device taught by Taylor'108 has the tip, arcuate section, and handle lying in a plane.

10. Claim 12: Taylor'108 discloses a an instrument for making an incision in a cardiac vessel containing a sterile penetration tip (2) to pierce the wall of a vessel

(column 3, lines 46-49); a body (4) extending from the tip; the body having a cutting edge (5) defined on an inner portion thereof in which the arcuate section contains at least one cutting guide defined thereon. This could be any marking on the blade such as the point at which the cutting edge (5) ends.

11. Claim 20: The tip taught by Taylor'108 is adapted to prevent tearing (column 2, lines 53-55).

12. Claim 21: Taylor'108 shows that the body (4) extends to a straight portion (7).

13. Claim 22: Taylor'108 discloses a method of forming an incision in a blood vessel that includes inserting the penetration tip (2) into a blood vessel, forming a puncture (column 3, lines 46-49); fixing the penetration tip so that it maintains a fixed position relative to an axis of the blood vessel (column 3, lines 49-59); and cutting a linear aperture guided by an extension of the penetration tip (column 3, line 59 to column 4, line 14).

14. Claim 23: Taylor'108 discloses penetrating the tip out of the blood vessel (column 3, line 65 to column 4, line 3).

15. Claim 25: Taylor'108 discloses that the width of the curved portion can be 0.07, but may vary depending on the application (column 4, lines 39-42).

16. Claims 26 and 27: Taylor'108 discloses that the surgeon can push lightly on the inside of the vessel with the tip in order to determine the location of the tip (and length of the incision) before making the cut (column 3, lines 62-66).

17. Claim 28 and 29: Taylor'108 discloses retracting the extension of the tip away from the vessel to form a cut (column 4,lines 4-14).

18. Claim 30: Taylor'108 discloses a method of cutting a blood vessel that includes inserting the front tip of a sickle-shaped cutter into a blood vessel (column 3, lines 46-49 and Figure 1a, 2); manipulating the tip to exit the blood vessel at a different point (column 3, line 65 to column 4, line 3); checking a marking on the cutter to estimate the resulting incision length (column 3, line 62 to 65); and retracting the cutter to cut the blood vessel (column 4,lines 4-14).

19. Claim 31: Taylor'108 discloses repositioning the tip prior to retracting (column 3, lines 49-57).

20. Claim 32: Taylor'108 discloses that the vessel is only punctured by the tip and is not damaged (column 4, lines 3-14 and column 3, lines 60-62).

21. Claim 44: Taylor'108 discloses a method of cutting an aperture that includes contacting a vessel with a marker having a fixed marking length (5) and cutting along the marking (column 3, line 46 to column 3, line 3).

22. Claim 45 and 46: Taylor'108 discloses measuring the marked aperture (AB) with the marker (5) (column 4, lines 4-14)

23. Claim 47: Taylor'108 discloses a method of cutting an aperture in a blood vessel including inserting a penetration tip into a blood vessel at a point (column 3, lines 47-49); visually identifies on the blood vessel a desired incision (column 3, lines 62-66) and then cutting according to the visual guiding (column 4, lines 3-14).

24. Claims 12, 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by McNeirney (US Patent 6,200,274).

25. Claim 12: McNeirney'274 teaches a device containing a sterile penetration tip (55) that is capable of piercing the wall of a blood vessel because of its size and shape; a body (10) extending from the tip; and a cutting guide (15) on the body (10).

26. Claim 14: McNeirney'274 teaches that the cutting guide contains a slot (20) sized to receive a cutting blade for cutting vessel walls.

27. Claim 15: McNeirney'274 teaches that that the slot (20) is marked with distance markers (30).

28. Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hart (US Patent 5,814,059).

29. Claim 33 and 34: Hart'059 discloses a flat elongate element (30) having a width; three slots (openings for tubes 34, 38, and 43) extending through the width capable of receiving a blood vessel (as demonstrated by tubes 34, 38, and 43) and a first edge gauge along the element (length of element).

30. Claim 35: In Hart'059's device, the second edge gauge (85) has a width between the diameter of the largest opening (38) and the two smaller openings (34, 43).

31. Claim 36: Hart'059 discloses a marking section (opening of edge gauge 85) so that a surgeon can mark the vessel.

32. Claim 37: The device taught by Hart'059 has a marking section at the bottom edge of the end gauge.

33. Claims 38-40 and 42-43 rejected under 35 U.S.C. 102(b) as being anticipated by Montgomery (US Patent 5,197,465).

34. Claim 38: Montgomery'465 discloses a marking evaluator containing a first enlongate element having a width (22); a gauge along the element (30); and a marking section (34) that is capable of marking a blood vessel because of its disclosed use in a tracheotomy.

35. Claim 39: Montgomery'465 teaches that the smallest leg is approximately 6 mm (column 2, lines 7-8). It is clear from the pictures that the distance between gauges (30 and 30) is smaller in diameter than the thinnest leg therefore, the first dimension is less than 6 mm.

36. Claim 42: Montgomery'465 discloses a second edge gauge (perpendicular to 34) and a second dimensions and marking section (width of 14).

37. Claim 40 and 43: The marking section (34) taught by Montgomery'465 is at the distal end of the gauge (Figure 1).

Claim Rejections - 35 USC § 103

38. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

39. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

40. Claims 8-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor'108.

41. Taylor'108 teaches the device of Claims 8-11, except for the specific dimensions. However, it would be obvious to one skilled in the art to make a cutting device at these dimensions because the device taught by Taylor'108 is intended for the same application (cutting blood vessels) as applicant's device.

42. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNeirney'274.

43. Claim 16 and 17: McNeirney'274 teaches that his device can be made to accommodate a variety of sizes (column 2, lines 57-68). Therefore it would have been obvious to one skilled in the art at the time the invention was made to make the ruler portion taught by McNeirney'274 smaller in order to perform operations requiring smaller penetration depths.

44. **Claims 13, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNeirney'274, as applied to Claim 12, in further view of Blatter, et al. (US Patent 2002/0058955).**

45. McNeirney'274 teaches the limitations of Claims 14, 18 and 19 except for the use of a frame.

46. Claim 13, 18 and 19: Blatter'955 teaches a frame (300) with a cutter (400) for performing an anastomosis that locks the vessel wall between the frame and the body

(410) of the cutter device (400). Blatter'955 teaches stops (314a) for attaching the frame to the vessel and for preventing the cutter from penetrating the device too far into the vessel. Further, Blatter'955 teaches that the cutter (400) is pivotally connected to the frame. It would have been obvious to modify the device taught by McNeirney'274 with the frame taught by Blatter'955 because the frame requires that the cutter fit through the frame, keeping the incision from being too large and creates an attachment site for a second vessel during an anastomosis procedure.

47. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor'108, as applied to Claim 22, in further view of Blatter'955.

48. Taylor'108 discloses the limitations of Claim 24 except for the use of a frame.

49. Blatter'955 teaches the use of locking a frame (300) to a blood vessel in order to hold a connector on the blood vessel. Therefore it would have been obvious to one skilled in the art at the time of the invention to lock a frame onto a blood vessel to maintain the incision in an open configuration so that a procedure can be performed.

50. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery'465.

51. Montgomery'465 teaches the limitations of Claim 38, except for the use of a protective cap. Caps to protect sterile devices are well known in the art in order to keep various devices free of germs. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a cap on any sterile marking section in order to keep the device free of germs and away from the patient when the device is being used.

Conclusion

52. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Bramlet (US Patent 5,649,946).

53. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

54. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

55. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER